

S I L L S C U M M I S & G R O S S
A PROFESSIONAL CORPORATION

The Legal Center
One Riverfront Plaza
Newark, New Jersey 07102-5400
Tel: 973-643-7000
Fax: 973-643-6500

Jeffrey J. Greenbaum
Member
Direct Dial: (973) 643-5430
E-mail: jgreenbaum@sillscummis.com

October 22, 2024

By ECF

Honorable Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102

Re: **United States ex rel. Silbersher v. Janssen Biotech Inc., et al.,**
Civil Action No. 19-12107 (MEF-SDA)

Dear Judge Arpert:

Defendants Johnson & Johnson, Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC (collectively, “Defendants”) submit this letter in the above-captioned matter pursuant to Local Civil Rule 37.1 governing discovery disputes, the Court’s Order referring discovery disputes to the Special Master (ECF No. 331), and the Special Master’s Order regarding unresolved discovery issues (ECF No. 337).

Relator has failed to provide Defendants with “all facts or data considered by” his expert witnesses, as required by Federal Rule of Civil Procedure 26(a)(2)(B)(ii). Defendants respectfully urge the Court to order Relator to serve corrected expert reports disclosing all materials “considered” by his experts and to produce any such materials in conjunction with serving corrected reports. As stated below, the parties have met and conferred on this matter, but are at an impasse.

In failing to provide all of the information required to be produced by Rule 26(a)(2)(B)(ii), or alternatively by failing to confirm that what has been disclosed for each expert reflects the full universe of required disclosures, Relator has materially hobbled Defendants' ability to prepare their responsive case. Without a full set of relevant materials, Defendants cannot properly and fully prepare to depose Relator's experts—to understand what they relied upon, what they considered, or what they rejected, and why—and to then prepare our own responsive expert reports. Indeed, more than half our allotted time has now run with Relator still knowingly refusing to make a full and proper production.

I. Background

Relator served seven expert reports on the August 7, 2024 deadline established by the Court's scheduling order.¹ *See* ECF No. 335. These disclosures gave Defendants their first look at Relator's full case, and indeed his expert reports contain multiple theories, subjects, and contentions that Relator had never previously surfaced in this litigation. As just one example, while Relator's Complaint alleges that Defendants wrongfully excluded generic competition to Zytiga by obtaining a patent through supposedly false statements to the U.S. Patent and Trademark Office, one of Relator's experts opines that Defendants employed "multiple" *other* strategies to wrongfully exclude generics, such as "product hopping" and the improper use of "authorized generics."² These allegations appear nowhere in the Complaint.

Relator's expert reports are deficient for two reasons. *First*, the reports do not disclose all facts and data the experts "considered" in formulating their opinions, as Rule 26(a)(2)(B)(ii)

¹ Since the deadline, Relator has twice served amended versions of the report of his damages expert, Dr. Hal Singer, with the most recent amendment served on August 27, 2024. Relator also served an amended version of the report of Dr. Robert Femia on September 25, 2024. Defendants filed a motion to strike Dr. Singer's second amended report that is now under consideration by this Court. *See* ECF No. 372.

² Ex. A, Hyman Report Excerpts at 23–24.

demands. Instead, most of Relator’s expert reports purport to disclose only the materials the expert “relied upon”—a necessarily narrower category of information than the expert “considered.” *Second*, on multiple occasions, the experts describe the materials “relied upon” at an unreasonable level of generality—failing to specify, for example, the particular passages of lengthy books or articles they cite. This lack of particularity unnecessarily impedes Defendants’ ability to prepare rebuttals to these reports.

More than 70 days have passed since Relator’s expert reports were due, and he still has not cured these deficiencies. Relator has not served corrected reports from his experts disclosing all facts and data considered by them, and has not produced all such information to Defendants.

Defendants identified these deficiencies in Relator’s expert reports soon after reviewing them, and contacted Relator on August 22, 2024, to request that he produce a complete, Bates-stamped production of all of the materials considered by his experts in forming their opinions. *See* Ex. B at 19 (Defendants’ August 22 Email). Defendants also requested that Relator produce the backup files used by his damages expert, Dr. Singer, which should have been produced with his report on August 7. Relator did not cure that deficiency for a month, finally producing such materials on September 6.

During the parties’ initial meet-and confer session, Relator acknowledged that most of his expert reports stated that they had disclosed only the materials “relied upon” in forming the expert’s opinion, and Relator proposed that the parties enter into a joint stipulation stating that only information “relied upon” by an expert witness would be disclosed in all expert reports in this matter. This is a substantially narrower category of materials than Rule 26 requires an expert to provide in a report—*i.e.*, “the facts or data *considered*” by the expert. Fed. R. Civ. P. 26(a)(2)(B)(ii) (emphasis added).

If Relator wished to negotiate for a narrower disclosure than Rule 26 requires, he should

have initiated that negotiation *before* his expert reports were due. Instead, he chose to file non-compliant reports on the deadline, and wait for Defendants to challenge them.

This unnecessarily prejudiced Defendants' preparation of their responsive case. Instead of receiving the set of materials Rule 26 requires on the date established by the scheduling order, Defendants have been forced to spend more than two months of the response period attempting to cajole Relator to comply with the Rule.

Those efforts have largely been unsuccessful. Following the parties' initial meet and confer, Defendants continued to request that Relator comply with Rule 26's requirements for expert disclosures to no avail. Relator's positions during the parties' meet-and-confers have shifted over time. At bottom, however, Relator has simply failed to cure the deficiencies in his expert disclosures despite over 70 days of discussion.

On September 25, Relator represented that each of his experts "*intended*" to disclose all facts or data they "*considered*" in forming their opinion, but—more than six weeks after his expert reports were due—Relator was still in the process of "*reconfirming*" with each of them whether or not they *actually* did so. Ex. B at 8–9 (Relator's Sept. 25 email) (emphasis added). In that same communication, Relator acknowledged that at least one of the experts did not make a proper disclosure on the deadline: Relator served an amended report for Robert Femia, which added "six references" that were not disclosed in the original report. *Id.*

Since then, despite over 70 days of discussion, Relator has failed to confirm that his remaining reports actually complied with Rule 26, and failed to file amended reports certifying as much.

Further, Relator continues to argue that he can exclude certain information from his disclosures of materials the experts "*considered*." The parties therefore remain at an impasse over the scope of Relator's expert disclosure obligation. While Relator has retreated from his position

that experts should only disclose information “relied upon,” rather than “considered,” Relator now argues that Rule 26(a)(2)(B)(ii) does not require that expert reports disclose information that was “screened” by the expert—*i.e.*, reviewed but not relied upon, either as not relevant or not material to the analysis. This “screening” exemption is vague and ambiguous and has no foundation whatsoever in Rule 26(a)(2)(B)(ii). Defendants simply seek the disclosure of materials “considered” by the expert, as the Rule commands.

Even under Relator’s misguided interpretation of Rule 26, he still is not in compliance. As of the date of this filing, Relator has disclosed *some* additional materials considered by two of his seven experts. Ex. B at 8–9 (Relator’s September 25 email); *id.* at 5 (Relator’s October 9 email). But Relator still has not served corrected reports from *any* of the seven experts certifying that their reports contain all the facts and data “considered” in forming their opinions. And Relator has not retreated from his incorrect position that he can exclude materials “screened” by the experts from his disclosures of materials they “considered.”

Finally, Relator still has not produced all materials considered by at least five experts. This includes copies of the relevant pages from the books, treatises, and other non-electronic sources considered by Relator’s experts. These are necessary for Defendants to ascertain which portion(s) of these materials bear on their opinions, particularly because many of Relator’s experts’ citations neglect to include pincites identifying the pages or chapters the expert considered.

II. Argument

A. Relator Must Disclose All Facts and Data “Considered” By His Experts.

Relators’ expert reports are deficient. By disclosing only the material “relied upon” in forming their opinions, each of Relator’s experts failed to comply with Rule 26(a)(2)(B)’s requirement that an expert report contain “the facts or data *considered* by the witness in forming [the expert opinion].” Fed. R. Civ. P. 26(a)(2)(B)(ii) (emphasis added).

This category of materials that must be disclosed necessarily is broader than those “relied upon” by an expert. *See Rule 26(a)(2)(B), 2010 Amendment Advisory Committee Note (“The disclosure obligation extends to any facts or data ‘considered’ by the expert in forming the opinions to be expressed, not only those relied upon by the expert.”). “The term ‘considered’ means information the expert reviewed, read, reflected on, or used in reaching his or her opinion.”* *FTC v. Lane-Labs, USA, Inc.*, No. 00-cv-3174, 2008 WL 4003927, at *1 (D.N.J. Aug. 25, 2008). Consequently, courts have interpreted Rule 26(a)(2)(B)(ii) to require “the disclosure of all information a testifying expert ‘generates, reviews, reflects upon, reads, and/or uses in connection with the formulation of his opinions, even if such information is ultimately rejected.’” *Williams v. First Student, Inc.*, No. 20-1176, 2023 WL 2063166, at *5 (D.N.J. Feb. 17, 2023) (quoting *Synthes Spine Co., L.P. v. Walden*, 232 F.R.D. 460, 463 (E.D. Pa. 2005)).

Relator’s expert reports fail to comply with this requirement:

- *Dr. Hal J. Singer* discloses only the materials that he “*relied upon*” for his report, not all facts and data that he *considered*. Ex. C, Singer Second Am. Report Excerpts ¶ 3; *id.* App. 1.
- *Dr. David A. Hyman* discloses materials “referenced or relied upon,” but not all facts and data he considered. Ex. A ¶ 2; *id.* App. B.
- *Dr. Mark Ratain* states that he “rel[ied] upon” documents cited in his report, and also was “provided access to” certain other materials not cited in the report. But he fails to make the simple statement required by the Rule certifying whether or not the report discloses all facts and data he considered. Ex. D, Ratain Report Excerpts at 2–3.
- *Dr. Jon Edward Clark* cites documents he “reviewed,” but fails provide the statement required by the Rule certifying whether or not the report discloses all facts and data he considered. Ex. E, Clark Report Excerpts ¶ 4 & Attachment B.
- Finally, three experts—*Robert Bahr*, *Robert Femia*,³ and *Sean Tu*—provide the materials they “considered.” While these statements use the language required by the Rule, these experts’ reports remain deficient to the extent Relator is withholding

³ Dr. Femia’s original report, served on the August 7 deadline, improperly disclosed only materials he “relied upon.” His Amended Report, served more than six weeks later, on September 25, disclosed what he “considered.”

information they “screened,” based on his misguided interpretation of the Rule’s requirements.

In sum, four of Relator’s experts improperly limited their disclosures only to material that the expert “relied upon” in forming their opinion. These four reports are deficient on their face. The other three experts appear to be improperly withholding information they “screened” from their disclosures, based on Relator’s argument regarding Rule 26’s requirements. Relator should be required to serve corrected reports signed by the experts, certifying that each of them has disclosed all materials “considered” in forming their opinions.

Relator’s claim that the experts can exclude information they “screened” from this disclosure is vague, ambiguous and untethered from the Rule itself. Indeed, this argument is squarely odds with the caselaw in this Circuit: If the expert “generate[d], review[ed], reflect[ed] upon, read[], and/or use[d]” information in the course of forming his or her opinion, then the expert must provide that information in the report, even if the expert “ultimately rejected” that information in the final analysis. *Williams*, 2023 WL 2063166, at *5 (quoting *Synthes Spine*, 323 F.R.D. at 463). There is no exception for materials that the expert reviewed and subsequently concluded were not relevant. Such information must be disclosed because understanding what materials an expert reviewed and rejected is essential to understanding the expert’s thought process and methodology, as well as to evaluating the expert’s care and diligence. In other words, the materials considered and rejected by an expert “often contain effective ammunition for cross-examination.” *Fid. Nat’l Title Ins. Co. of N.Y. v. Intercounty Nat’l Title Ins. Co.*, 412 F.3d 745, 751 (7th Cir. 2005). The Court should compel relator to serve corrected reports containing this information.

B. Relator Must Produce the Documents “Considered” By His Experts.

The Court should also direct Relator to produce all material considered by his experts. This

is vital to enable Defendants to properly and fully depose Relator’s expert witnesses and prepare rebuttal reports. Courts in this District routinely impose such a requirement upon litigants. *See, e.g., In re Benicar (Olmersartan) Prods. Liab. Litig.*, 319 F.R.D. 139, 141 n.4 (D.N.J. 2017) (“Records considered by trial experts in reaching their expert opinions must be produced.”).

Now more than two months after his expert reports were due, Relator has not produced this information for at least five of his seven experts. Although he has not yet done so, Relator says he will produce *some* materials considered by these experts, including “scientific articles or other references available electronically,” but he refuses to produce others, such as “larger reference books or treatises that are in physical print.”⁴

Neither Rule 26 nor the caselaw interpreting it supports the distinction Relator draws. “The purpose of Rule 26(a)(2)’s expert disclosure requirements is to eliminate surprise and provide the opposing party with enough information regarding the expert’s opinion and methodology to prepare efficiently for deposition, any pretrial motions[,] and trial.” *Cook v. Rockwell Int’l Corp.*, 580 F. Supp. 2d 1071, 1122 (D. Colo. 2006) (citing *Sylla-Sawdon v. Uniroyal Goodrich Tire Co.*, 47 F.3d 277, 284 (8th Cir. 1995); *Nguyen v. IBP, Inc.*, 162 F.R.D. 675, 682 (D. Kan. 1995)). Consistent with this purpose, the “overwhelming majority of courts”—including this Court—“have required the production of *any* information considered by a testifying expert in reaching his or her opinion.” *Lane-Labs*, 2008 WL 4003927, at *1 (emphasis added); *see also In re Benicar*, 319 F.R.D. at 140 (“A majority of courts have taken the pro-discovery position that pursuant to Rule 26(a)(2)(B), a party must disclose all information provided to its testifying expert for consideration in the expert’s report.” (cleaned up)). This should include both electronically available articles and portions of books that are easily scanned and converted to electronic form.

⁴ For the sake of clarity, as Relator is aware, Defendants’ request excludes: (1) deposition transcripts and exhibits from this litigation; (2) documents produced in this litigation; and (3) pleadings from this litigation.

Production of these non-electronic materials is also particularly appropriate in this case because Relator’s experts have failed to identify what within these sources was considered. For example, Dr. Femia’s Amended Report identifies three books that he purportedly “relied upon” in forming his opinions. Ex. F, Femia Am. Report Excerpts ¶¶ 9–11. But Dr. Femia does not identify, with pincites or otherwise, the specific portions of these books that he actually considered. For example, Dr. Femia cites entire books without citation to any specific chapter or page. It is implausible that Dr. Femia would have “considered” entire books rather than specific passages within those books. Dr. Hyman’s report is similarly deficient. On numerous occasions, he cites entire books, articles, and reports without any effort to point Defendants to the particular pages considered. *See, e.g.*, Hyman Report ¶ 22 n.12 (three reports, five articles, and one book chapter with zero pincites), ¶ 23 n.15 (four articles and one report with zero pincites), ¶ 34 n.27 (five reports and one article with zero pincites), ¶ 40 n.44 (five reports, one article, fifteen amicus briefs, and nine FTC statements, press releases, or filings with zero pincites); ¶ 49 n.69 (seven articles with zero pincites).

This unnecessarily complicates Defendants’ ability to prepare their responsive case and inappropriately hides the ball as to what these experts considered. This makes production of these materials—consistent with the position of the numerous courts cited above—all the more essential.

Moreover, there should be no “material burden for [Relator’s] experts to produce” these materials because the experts (presumably) already have access to all of them in preparing their reports. *In re Benicar*, 319 F.R.D. at 142. In contrast, obtaining the books, treatises, and other non-electronic sources cited by Relator’s experts will be burdensome, costly, and, most importantly, time-consuming for Defendants given that Relator has already deprived them of more than two months allotted to prepare rebuttal reports.

Relator recently has stated that he may produce such sources if Defendants show they are

“unable to obtain” them. This does not cure the problem and unnecessarily shifts the burden on these matters to Defendants. Under Rule 26 and the Scheduling Order, Relator should have provided Defendants with all of this information on August 7, when his expert reports were due. Instead, Relator has consumed more than half of Defendants’ period for responsive reports resisting compliance with the Rule. Nothing in Rule 26 requires Defendants to hunt for Relator’s sources or make some undefined showing of how difficult they are to obtain. Further, enforcing such a rule would be particularly inappropriate in this case, where multiple references in Relator’s expert reports lack pincites directing Defendants to the particular pages the expert considered—a customary protocol that is fair to expect of an expert analysis submitted in a federal court.

Accordingly, the Court should compel Relator to produce all “considered” materials, as required by Rule 26(a)(2)(B)(ii). *See id.* (requiring plaintiff’s experts to “produce or make available for inspection by defendants the medical records they ‘considered’ in reaching their expert opinions”).

* * *

For the foregoing reasons, Defendants respectfully request that the Court direct Relator to serve corrected reports disclose all materials considered by his experts and to produce any such materials in conjunction with serving the corrected reports. Relator has delayed substantially beyond the due date for his expert reports in producing these materials. Defendants therefore respectfully ask the Court to direct Relator to provide Defendants with this information no later than ten (10) days from the date of the Court’s order.

October 22, 2024

SILLS CUMMIS & GROSS P.C.

By: /s/ Jeffrey J. Greenbaum _____

JEFFREY J. GREENBAUM

jgreenbaum@sillscummis.com

GREGORY E. REID

greid@sillscummis.com

One Riverfront Plaza

Newark, New Jersey 07102

Phone: (973) 643-7000

Facsimile: (973) 643-6500

SIDLEY AUSTIN LLP

GORDON D. TODD (*pro hac vice*)

gtodd@sidley.com

BRIAN P. MORRISSEY (*pro hac vice*)

bmorriss@sidley.com

LAUREN KATZEFF (*pro hac vice*)

lkatzeff@sidley.com

ALARIC R. SMITH (*pro hac vice*)

alaric.smith@sidley.com

1501 K Street, N.W.

Washington, DC 20005

Attorneys for Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson